EUROPEAN COMMISSION

Brussels, 3.10.2011
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COMMISSION IMPLEMENTING DECISION

of 3.10.2011

amending the marketing authorisation granted by Decision C(2004)1765 for "Lysodren - Mitotane", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the notification submitted by Laboratoire HRA Pharma, under the first subparagraph of Article 14(1) of Regulation (EC) No 1234/2008,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the minor variations of type IA, notified between 16 February 2011 and 9 September 2011, and of the need to amend the decision granting the marketing authorisation.

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 334, 12.12.2008, p. 7.
3 OJ L 311, 28.11.2001, p. 67.

(2) Laboratoire HRA Pharma has submitted, under Article 61(3) of Directive 2001/83/EC, notifications for changes to an aspect of the labelling or the package leaflet, which are not yet included in Decision C(2004)1765 of 28 April 2004.

(3) The marketing authorisation should be updated and Decision C(2004)1765 of 28 April 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(4) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)1765 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)1765 is amended as follows:

1) The following notifications for minor variations are added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMEA/H/C/521/IA/9/G	A.5.a), B.II.b.2.b).1 (EU/1/04/273/001)

2) The following notifications for changes to aspects of the labelling or the package leaflet are added to the marketing authorisation:

Application number	Annex (EU numbers affected)
EMEA/H/C/521/N/10	IIIB (EU/1/04/273/001)
EMEA/H/C/521/N/8	IIIB (EU/1/04/273/001)

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Laboratoire HRA Pharma, 15, rue Béranger, 75003 Paris, France.

Done at Brussels, on 3.10.2011.

For the Commission
Paola TESTORI COGGI
Director-General